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10/518,432

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Alan Murray

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EXAMINER

SWARTZ, RODNEY P

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

09/22/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/518,432

Applicant(s)

MURRAY ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 11, 12, 15, 33-40, 42-47, 50 and 51 is/are allowed.
- 6) ☒ Claim(s) 2-5, 13, 14, 18, 20-32, 41, 48, 49 and 52 is/are rejected.
- 7) ☒ Claim(s) 6-10, 16, 17, 19 and 27 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 25 July 2008 has been entered.

Claims 1-5, 8, 11, 22, 24, and 39-41 have been amended. New claim 52 has been added.

2. Claims 1-52 are pending and under consideration.

Objections/Rejections Withdrawn

3. The objection to claim 1 is withdrawn in light of the amendment of the claims.
4. The rejection of claims 1-51 under 35 U.S.C. 112, second paragraph, indefiniteness for "functionally equivalent variant" is withdrawn in light of the amendment of the claims.
5. The rejection of claim 2 under 35 U.S.C. 112, second paragraph, is withdrawn in light of the amendment of the claim.

Claim Objections

6. Claim 10 is objected to because of the following informalities: there should be an "and" following step b. Appropriate correction is required.
7. Claim 27 is objected to because of the following informalities: line 3, "comprising of at least" should be "comprising at least". Appropriate correction is required.

Double Patenting

8. Claim 6 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The recitation that the polypeptide of claim 1 be "obtainable" from a bacterium does not actually require that polypeptide be obtained from a bacterium. Thus, the polypeptide may be obtained from any method/source.

9. Claim 7 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The recitation that the polypeptide of claim 1 be "obtainable" from specific bacteria does not actually require that polypeptide be obtained from said specific bacteria. Thus, the polypeptide may be obtained from any method/source.

10. Claims 8 and 9 are objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The recitation that the polypeptide of claim 1 be "obtainable" from a heterologous transformed host, e.g., *E. coli*, does not actually require that polypeptide be obtained from said transformed host. Thus, the polypeptide may be obtained from any method/source.

11. Claim 16 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The claimed composition comprises only 1 component, a polypeptide as claimed in claim 1, and, therefore is a duplicate of claim 1. The recitation of intended use places no patentable criterion on the claim.

12. Claim 17 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 11. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The claimed composition comprises only 1 component, a polynucleotide according to claim 11, and, therefore is a duplicate of claim 11. The recitation of intended use places no patentable criterion on the claim.

13. Claim 19 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 14. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim

to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The claimed composition comprises only 1 component, an antibody according to claim 14, and, therefore is a duplicate of claim 14. The recitation of intended use places no patentable criterion on the claim.

Claim Rejections - 35 USC § 112

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is dependent from claim 1. Claim 1 is a polypeptide "comprising" a listed sequence. Claim 2 recites: The polypeptide as claimed in claim 1 wherein "the sequence" has greater than 97% identity with SEQ ID NO:1. It is unclear if "the sequence" in claim 2 is referring to the claimed polypeptide of claim 1 or the sequence which the claimed polypeptide "comprises".

16. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is dependent from claim 1. Claim 1 is a polypeptide "comprising" a listed sequence. Claim 3 recites: The polypeptide as claimed in claim 1 wherein "the sequence" has greater than 99% identity with SEQ ID NO:1. It is unclear if "the sequence" in claim 3 is referring to the claimed polypeptide of claim 1 or the sequence which the claimed polypeptide "comprises".

17. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is dependent from claim 1. Claim 1 is a polypeptide "comprising" a listed sequence. Claim 4 recites: The polypeptide as claimed in claim 1 wherein "the sequence" has greater than 99% identity with the sequence of amino acids 20 to 235 of SEQ ID NO:1. It is unclear if "the sequence" in claim 4 is referring to the claimed polypeptide of claim 1 or the sequence which the claimed polypeptide "comprises".

18. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is dependent from claim 4. Claim 5 recites: The polypeptide as claimed in claim 4 wherein "the sequence" the sequence of amino acids 20 to 235 of SEQ ID NO:1. It is unclear if "the sequence" in claim 5 is referring to the claimed polypeptide of claim 4 or the sequence which the claimed polypeptide "comprises".

19. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to ≥ 1 primer capable of amplifying a polynucleotide which encodes a polypeptide as claimed in claim 1.

Claim 1 is drawn to a polypeptide "comprising" one of four listed sequences. Because of the open language, the claimed polypeptide may have any number of unknown amino acids on either end of the listed sequences.

Therefore, it is unclear how one identifies a primer capable of amplifying a polynucleotide which encodes these unknown regions.

20. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to an antibody capable of binding a polypeptide as defined in claim 4.

Claim 4 is drawn to a polypeptide comprising a sequence with >99% identity with a listed sequence. Because of the open language, the claimed polypeptide may have any number of unknown amino acids on either end of the listed sequences.

Thus, it is unclear how one identifies an antibody capable of binding to these unknown regions.

21. Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to a diagnostic composition comprising ≥ 1 oligonucleotide or polynucleotide primer capable of amplifying a polynucleotide which encodes a polypeptide as claimed in claim 1.

Claim 1 is drawn to a polypeptide "comprising" one of four listed sequences. Because of the open language, the claimed polypeptide may have any number of unknown amino acids on either end of the listed sequences.

Therefore, it is unclear how one identifies a primer capable of amplifying a polynucleotide which encodes these unknown regions.

22. Claims 20-23, 29, and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At least one embodiment of claim 20 is a method of detecting Johnes's disease comprising contacting either the animal or a sample from the animal with a polypeptide as claimed in claim 1 and detecting an immune response indicative of the presence of *M. avium* subspecies *paratuberculosis*.

Claim 1 is drawn to a polypeptide "comprising" one of four listed sequences. Because of the open language, the claimed polypeptide may have any number of unknown amino acids on either end of the listed sequences.

Therefore, it is unclear how one distinguishes between an immune response to these unknown regions (which may not be indicative of the presence of *M. avium* subspecies *paratuberculosis*) and an immune response to the listed sequences.

Claims 21-23, 29 and 48 depend from claim 20, but do not clarify the issue.

23. Claims 24-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At least one embodiment of claim 24 is a method of detecting Johnne's disease comprising contacting a sample from the animal with an antibody capable of binding a polypeptide "comprising" one of two listed sequences, or a composition comprising an antibody capable of binding a polypeptide "comprising" one of two listed sequences, and detecting a polypeptide which binds to the antibody.

Because of the open language, the claimed polypeptide may have any number of unknown amino acids on either end of the listed sequences.

Therefore, is it unclear how one distinguishes between an antibody which binds to these unknown regions (which may not be indicative of the presence of *M. avium* subspecies *paratuberculosis*) and an antibody which binds to the the listed sequences.

Claims 25 and 26 depend from claim 24, but do not clarify the issue.

24. Claims 27 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At least one embodiment of claim 27 is a method of detecting Johnne's disease comprising contacting a sample from the animal with a composition comprising ≥ 1 oligonucleotide or polynucleotide primers capable of amplifying a polynucleotide which encodes a polypeptide as claimed in claim 4.

Claim 4 is drawn to a polypeptide comprising a sequence with >99% identity with a listed sequence. Because of the open language, the claimed polypeptide may have any number of unknown amino acids on either end of the listed sequences.

Therefore, is it unclear how one distinguishes between a primer capable of amplifying a polynucleotide which encodes these unknown regions (which may not be indicative of the

presence of *M. avium* subspecies *paratuberculosis*) and primers which amplify a polynucleotide which encodes the listed sequence.

Claims 28 depends from claim 27, but does not clarify the issue.

25. Claims 30-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At least one embodiment of claim 30 is a method of detecting Johnne's disease comprising contacting a sample from the animal with a composition comprising a polynucleotide capable of binding to a polynucleotide which encodes a polypeptide as claimed in claim 4.

Claim 4 is drawn to a polypeptide comprising a sequence with >99% identity with a listed sequence. Because of the open language, the claimed polypeptide may have any number of unknown amino acids on either end of the listed sequences.

Therefore, is it unclear how one distinguishes between a polynucleotide capable of binding to a polynucleotide which encodes these unknown regions (which may not be indicative of the presence of *M. avium* subspecies *paratuberculosis*) and polynucleotides which bind to a polynucleotide which encodes the listed sequence.

Claims 31 and 32 depend from claim 30, but does not clarify the issue.

26. Claim 41 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to a kit comprising a polypeptide as claimed in claim 1 and an antibody that binds said polypeptide.

Claim 1 is drawn to a polypeptide "comprising" one of four listed sequences. Because of the open language, the claimed polypeptide may have any number of unknown amino acids on either end of the listed sequences.

Thus, it is unclear what antibody is encompassed by said claim because one does not know what it binds to, i.e., the known or unknown regions.

27. Claim 49 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to "the method as claimed in claim 47". It is unclear what is being claimed because claim 47 is a product, not a method. In addition, there is no antecedent basis for "wherein the animal" because none of the prior claims recite any animal.

28. Claim 52 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to an antibody capable of binding a polypeptide as defined in claim 5.

Claim 5 is drawn to a polypeptide "comprising" amino acids 20-235 of SEQ ID NO:1. Because of the open language, the claimed polypeptide may have any number of unknown amino acids on either end of the listed sequences.

Thus, it is unclear what antibody is encompassed by said claim because one does not know what it binds to, i.e., the known or unknown regions.

Conclusion

29. Claims 2-10, 13, 14, 16-32, 41, and 48-52 are rejected or objected to.

30. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisors, Shannon Foley (571)272-0898, and Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

September 22, 2008

Application Number**Application/Control No.**

10/518,432

**Applicant(s)/Patent under
Reexamination**

MURRAY ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645